

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

W. R. GRACE & CO.-CONN.,

Plaintiff,

v.

ELYSIUM HEALTH, INC.,

Defendant.

C.A. No. 20-1098-GBW

MEMORANDUM ORDER

Pending before this Court is Defendant Elysium Health Inc.’s (“Elysium”) Motion for Reargument or, in the Alternative, Motion for Leave to Amend Answer and Counterclaims. D.I. 240 (the “Motion”). Elysium first seeks reargument on whether Elysium properly pled inequitable conduct claims that pertained to David Short in its Amended Answer and Counterclaims, D.I. 113. Alternatively, Elysium seeks leave to file its Second Amended Answer and Counterclaims, D.I. 240, Ex. 1, with additional evidence against David Short.

I. BACKGROUND

On December 15, 2021, Elysium filed a Motion for Leave to Amend its Answer and Counterclaims to assert a defense and counterclaims that U.S. Patent Nos. 10,233,207 (“the ’207 patent”)¹ and 10,323,058 (“the ’058 patent”) (collectively, “the Form I patents”), and U.S. Patent No. 10,189,872 (“the ’872 patent” or “the Form II patent”) (collectively, “the Asserted Patents” or the “Patents-in-Suit”) are unenforceable for inequitable conduct. D.I. 59. The Court denied that motion, D.I. 59, with leave to file a further amended answer and counterclaims on or before

¹ The parties filed a Stipulated Order of Voluntary Dismissal of Certain Asserted Claims and Counterclaims, D.I. 301, that dismissed all asserted claims of the ’207 patent.

May 5, 2022. *See* D.I. 120 (April 14, 2022 Hearing Tr.) at 83:3-85:20 (“So what I’m going to do is, I’m going to deny the motion, but give three weeks to file an amended [pleading] that sets forth the inequitable conduct claim.”). On May 5, 2022, Elysium filed its Amended Answer and Counterclaims. D.I. 113. On May 26, 2022, Plaintiff W.R. Grace & Co.-Conn. (“Grace”) timely filed a Motion to Dismiss Elysium’s inequitable conduct counterclaims and strike the related affirmative defense. D.I. 136. On February 10, 2023, this Court granted-in-part and denied-in-part Grace’s Motion to Dismiss. D.I. 225. The Court found that Elysium had adequately alleged “but-for materiality and specific intent as to [Erik] Carlson and [Brett] Reynolds,” to support inequitable conduct claims in its Amended Answer, D.I. 113, “but not as to other Grace employees.” D.I. 225 at 10.

Elysium moves for reargument of the Motion to Dismiss, D.I. 136, specifically addressing whether inequitable conduct had been adequately pled as to a third Grace employee, David Short. D.I. 240. In the alternative, Elysium seeks leave to file a Second Amended Answer and Counterclaims, D.I. 240-1, to more specifically tie Mr. Short to its factual allegations.² Grace filed a response in opposition to this Motion on March 10, 2023. D.I. 257. This Motion was deferred to be decided at a later date as requested by the parties. D.I. 289 at 2.

II. ANALYSIS

1. Motion for Reargument

a. Rule 59(e) Legal Standard

The purpose of a motion for reconsideration or reargument “is to correct manifest errors of law or fact or to present newly discovered evidence.” *Max’s Seafood Cafe v. Quinteros*, 176 F.3d 669, 677 (3d Cir. 1999) (citation omitted). To succeed on such a motion, a party must

² The parties stated in the Proposed Pretrial Order that, if the motion to amend is granted, the parties do not anticipate further discovery. D.I. 288 ¶ 18.

demonstrate one of the following: “(1) an intervening change in the controlling law; (2) the availability of new evidence that was not available when the court [issued its order]; or (3) the need to correct a clear error of law or fact or to prevent manifest injustice.” *Id.* “A motion for reargument is not an appropriate vehicle to reargue issues that the court has already considered and decided.” *Mirtech, Inc. v. Agrofresh, Inc.*, C.A. No. 20-1170-RGA, 2023 WL 3996618, at *3 (D. Del. June 14, 2023).

b. Discussion

“Whether inequitable conduct has been pleaded with particularity under Rule 9(b) is a question covered by Federal Circuit law.” *Exergen Corp. v. Wal-Mart Stores, Inc.*, 575 F.3d 1312, 1318 (Fed. Cir. 2009).

[T]o plead the “circumstances” of inequitable conduct with the requisite “particularity” under Rule 9(b), the pleading must identify the specific who, what, when, where, and how of the material misrepresentation or omission committed before the PTO. Moreover, although “knowledge” and “intent” may be averred generally, a pleading of inequitable conduct under Rule 9(b) must include sufficient allegations of underlying facts from which a court may reasonably infer that a specific individual (1) knew of the withheld material information or of the falsity of the material misrepresentation, and (2) withheld or misrepresented this information with a specific intent to deceive the PTO.

Id. at 1328-29.

Elysium argues that “the Court inadvertently overlooked allegations as to Mr. Short in Elysium’s pleading[.]” DI. 240 at 7. Specifically, Elysium asserts that it sufficiently pled (1) Mr. Short knew Grace’s pre-critical date sales were material and he was involved in the prosecution of the Asserted Patents, and (2) Mr. Short’s intent to withhold that information or, at a minimum, his intent to withhold is a reasonable inference (both on his own behalf and on behalf of Mr. Reynolds) under the *Exergen* standard. *Id.* at 6-7.

In support of its argument, Elysium redirects this Court to the scavenger hunt it placed in its Amended Answer and Counterclaims. D.I. 113. Elysium claims it identified Mr. Short when it accused “other individuals at Grace (including at a minimum Brett Reynolds, Grace’s Global Business Director, and *those involved in the communications discussed beginning at paragraph 67, below*).” D.I. 113 ¶ 45 (emphasis added); D.I. 240 at 3. Certainly “other individuals at Grace” would not be specific enough. *XpertUniverse, Inc. v. Cisco Sys., Inc.*, 868 F. Supp. 2d 376, 381 (D. Del. 2012). So, in parenthesis, Elysium adds “including at a minimum Brett Reynolds, Grace’s Global Business Director, and those involved in the communications discussed beginning at paragraph 67, below.” D.I. 113 at 32, ¶ 45.c.

The Court, in its attempt to find the accused individuals, continues by reading paragraph 67 which broadly states:

Documents produced by Grace demonstrate that other Grace employees, including employees involved in patent prosecution, also were aware that Grace’s crystalline nicotinamide riboside chloride was the subject of commercial offers for sale and actual sales to ChromaDex at least one year before the priority date of the Asserted Patents and knew of its materiality to obtaining the Asserted Patents.

Id. at 40, ¶ 67.

The Court notes that there are no citations to any documents in paragraph 67. Nonetheless, the Court reads on, since Elysium stated that the communications identifying the accused persons “[began] at 67.” *Id.* at 32, ¶ 45.c.

Paragraph 68 of the Amended Answer and Counterclaims describes a document that this Court previously relied upon in denying the Motion to Dismiss Elysium’s inequitable conduct claims against Brett Reynolds (who is also expressly named in ¶ 45 as an accused individual). D.I. 225 9 n.3. But David Short is not on that document.

Paragraph 69 of the Amended Answer and Counterclaims states “[t]he log of documents provided by Grace in this matter identifies documents withheld as purportedly privileged or immune.” D.I. 113 at 41, ¶ 69. It is unclear if a privilege log produced by Grace would qualify as “communications discussed beginning at paragraph 67,” *see* D.I. 113 at 32, ¶ 45.c. Even if the reader made that assumption, the privilege log cannot alone show that “other Grace employees” were “aware that Grace’s crystalline nicotinamide riboside chloride was the subject of commercial offers for sale and actual sales to ChromaDex at least one year before the priority date of the Asserted Patents and knew of its materiality to obtaining the Asserted Patents.” D.I. 113 at 40, ¶ 67. *See Knorr-Bremse Systeme Fuer Nutzfahrzeuge GmbH v. Dana Corp.*, 383 F.3d 1337, 1344-45 (Fed. Cir. 2004) (Courts “have declined to impose adverse inferences on invocation of the attorney-client privilege.”).

In the Amended Answer and Counterclaims, Elysium points to three documents listed on the privilege log with the same date as the email referenced in paragraph 68—September 25, 2018—to show that “Mr. Reynolds [a known accused individual] exchanged email messages regarding ‘patent protection’ to David Short, Grace’s Global Business & Technology Manager and Brian Graves, Grace’s Global Business Manager.” D.I. 113 at 41, ¶ 69. Even if the privilege log listings were enough to name David Short as a “who” under *Exergen*, the Court still finds that the Amended Answer and Counterclaims do not allege or show that Mr. Short was involved in the prosecution of the Asserted Patents. D.I. 225 at 9-10.

In its briefing, Elysium argues that “Mr. Short reviewed the patent applications” and that this, “combined with [e]mails regarding patent protection that included Mr. Short at the same time Mr. Reynolds [] was asking about early batch sales, while Mr. Short was compiling information in his ‘NRCI First sale’ folder, supports a reasonable inference of his role in

prosecution of the Asserted Patents, as set out in Elysium’s pleading.” D.I. 240 at 7. However, Elysium’s pleading does not assert that David Short reviewed patent applications. Elysium’s pleading also does not assert that David Short was compiling information in an NRCI First Sale folder.³ As for the “emails,” the privilege log describes three emails with Mr. Short as an “[e]mail concerning patent protection reflecting legal advice with associated email chain reflecting legal advice.” D.I. 113, Ex. 14. The description does not show that Mr. Short was involved in patent prosecution, and Elysium does not assert that Mr. Short was involved in patent prosecution in its pleading. Rather, Elysium asserts that “Grace’s decision to list these emails *involving Mr. Reynolds* on its privilege log is an admission that *patent prosecution counsel was aware of the prior sales* and in communication *with Mr. Reynolds* on this topic.” *Id.* at 41-42, ¶ 70 (emphasis added).

For these reasons, the Court finds that reargument is not warranted under the circumstances. Accordingly, Elysium’s Motion as it pertains to reargument is DENIED.

2. Motion for Leave to Amend

The Court next considers Elysium’s alternative motion—leave to file a Second Amended Answer, D.I. 240, Ex. 1. D.I. 240 at 8.

a. Rule 15 and Rule 16(b)(4) Legal Standard

“Leave to amend must generally be granted unless equitable considerations render it otherwise unjust.” *Arthur v. Maersk, Inc.*, 434 F.3d 196, 204 (3d Cir. 2006); *see also Foman v. Davis*, 371 U.S. 178, 182 (1962). “The Third Circuit has adopted a liberal approach to the amendment of pleadings.” *Id.* “In the absence of undue delay, bad faith, or dilatory motives on

³ The Amended Answer and Counterclaims cites to a certificate of analysis for a ChromaDex delivery found in Mr. Short’s files. D.I. 113 at 36, ¶ 60 & Ex. 10 (GRACE0039274). This is a different document than the document that Elysium cites to in its briefing as the “NRCI First sale” folder, GRACE0192453. D.I. 240 at 4, 7.

the part of the moving party, the amendment should be freely granted, unless it is futile or unfairly prejudicial to the non-moving party.” *Id.* (citations omitted). An amendment is futile if it “would fail to state a claim upon which relief could be granted.” *In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1434 (3d Cir. 1997). “The standard for assessing futility is the ‘same standard for legal sufficiency as applies under [Federal] Rule [of Civil Procedure] 12(b)(6).’” *Great W. Mining & Min. Co. v. Fox Rothschild, LLP*, 615 F.3d 159, 175 (3d Cir. 2010) (quoting *Shane v. Fauver*, 213 F.3d 113, 115 (3d Cir. 2000)).

If a motion to amend satisfies Rule 15, but the motion is filed after the deadline set for amendments under a scheduling order, the moving party must also satisfy Rule 16(b)(4) of the Federal Rules of Civil Procedure. *See E. Minerals & Chems. Co. v. Mahan*, 225 F.3d 330, 340 (3d Cir. 2000). Rule 16(b)(4) provides that “[a] schedule may be modified only for good cause and with the judge’s consent.” While Rule 15(a)(2) focuses on the question of prejudice to the non-moving party, Rule 16(b)(4) “focuses on the moving party’s burden to show due diligence.” *Race Tires Am., Inc. v. Hoosier Racing Tire Corp.*, 614 F.3d 57, 84 (3d Cir. 2010); *see also WebXchange Inc. v. Dell Inc.*, C.A. No. 08-132-JJF, 2010 WL 256547, at *2 (D. Del. Jan. 20, 2010) (“In contrast to Rule 15(a), the good cause standard under Rule 16(b) hinges on diligence of the movant, and not on prejudice to the non-moving party.”); *Roquette Freres v. SPI Pharma, Inc.*, C.A. No. 06-540-MPT, 2009 WL 1444835, at *4 (D. Del. May 21, 2009) (“The good cause element requires the movant to demonstrate that, despite diligence, the proposed claims could not have been reasonably sought in a timely manner.”). Thus, good cause is established if the amendment is not unduly delayed, i.e., if the movant shows that it acted diligently in filing its motion to amend. If the movant satisfies that requirement of Rule 16, leave to amend should be

granted unless there is a reason to deny leave, such as bad faith, prejudice to the non-moving party, or futility of the claims. *See Foman*, 371 U.S. at 182; *In re Burlington*, 114 F.3d at 1434.

b. Discussion

Elysium asserts that, after filing its Amended Answer and Counterclaims and the completion of the briefing on Grace's Motion to Dismiss the inequitable conduct claims, Elysium took Mr. Short's deposition and learned additional information that tied Mr. Short to the inequitable conduct claims. D.I. 240 at 9. For example, during his June 29 deposition, Mr. Short stated that he was "involved in reviewing patents, patent applications[.]" including the patent applications related to Form I and Form II NRC1. D.I. 240, Ex. 4 (Short Depo. Tr.) at 28:18-24, 96:16-21. Mr. Short also admitted to being aware of his duty to disclose material information to the patent office. *Id.* at 95:2-97:17. *See also id.* at 28:3-32:24; 95:22-96:21; 124:10-128:13; 132:21-134:8; 145:22-151:18.

1. Rule 16(b)(4) Analysis

In examining whether Elysium has good cause to amend under Rule 16(b)(4), the Court notes the following: The Amended Answer and Counterclaims, D.I. 113, was filed on May 5, 2022. Grace filed its Motion to Dismiss for failure to state a claim on May 26, 2022. D.I. 136. Briefing concluded on June 20, 2022. D.I. 155. Nine days later, Elysium took the deposition of David Short. D.I. 240, Ex. 4. The Court docketed its Memorandum Order granting-in-part, denying-in-part Plaintiff's Motion to Dismiss, D.I. 136, on February 10, 2023. D.I. 225. After the Court entered the Memorandum Order dismissing Elysium's inequitable conduct claims

against everyone except Erik Carlson and Brett Reynolds, Elysium filed the present Motion on February 24, 2023. D.I. 240.

Given Elysium's diligence, the Court finds there is good cause to allow the amendment. Indeed, the posture of this case closely resembles that in *Baxalta Inc. v. Bayer Healthcare LLC*. C.A. No. 17-1316-RGA-SRF, D.I. 604 at 7 (D. Del. Dec. 11, 2020). In the instant action, the depositions of David Short and Brett Reynolds did not give rise to new allegations of inequitable conduct. Instead, the depositions revealed details providing additional support for the pending inequitable conduct claims. Thus, delaying the present motion until after resolution of the motion to dismiss was appropriate under the circumstances of this case because Elysium could not be certain the pleadings were deficient until after a ruling was made on the motion to dismiss. *See id.*; *see also Victaulic*, 839 F.3d at 250 (finding good cause where the plaintiff promptly moved to amend after the district court ruled on a pending motion to dismiss).⁴

Moreover, the cases Grace cites in its briefing are distinguishable. D.I. 257 at 8-9. In those cases, the parties raised new claims, relying on information and evidence that was already in their possession for some time. For example, in *Carrier Corp. v. Goodman Global, Inc.*, the court denied the motion to amend where documents relied on were disclosed seven months ago and new claims would reopen discovery. 49 F. Supp. 3d 430, 433 (D. Del. 2014). In *Asahi Glass Co. v. Guardian Indus. Corp.*, the court denied the motion for leave to amend where "defendant's delay in moving to amend until March 4, 2011 [was] largely unexplained" and new

⁴ It should also be noted that "the mere fact that a [movant] files a motion to dismiss is not necessarily sufficient to put [the nonmovant] on notice that the court will find his complaint to be deficient." *United States ex rel. Customs Fraud Investigations, LLC v. Victaulic Co.*, 839 F.3d 242, 249 (3d Cir. 2016); *see also Fraunhofer-Gesellschaft Zur Forderung der angewandten Forschung e.V. v. Sirius XM Radio Inc.*, C.A. No. 17-184-JFB-SRF, 2018 WL 3425012, at *4 (D. Del. July 16, 2018) (finding that the plaintiff "satisfied the diligence standard under Rule 16(b)(4) by timely pursuing leave to amend following the issuance of the . . . Report and Recommendation."), *rev'd and remanded on other grounds*, 940 F.3d 1372 (Fed. Cir. 2019).

claims would reopen discovery. 276 F.R.D. 417 (D. Del. 2011). In *Pfizer Inc. v. Sandoz Inc.*, the court disagreed with the defendant that time reviewing a “tortuous” prosecution history record justified a four-month delay in filing their motion. C.A. No. 12-654-GMS-MPT, 2013 WL 5934635, at *3 (D. Del. Nov. 4, 2013). In *Genentech, Inc. v. Amgen, Inc.*, the defendant admitted it “had the ability in July 2019 to plead with particularity the proposed inequitable conduct claim and defense it [sought] to add to the case” but “wait[ed] until September 2019[.]” C.A. No. 17-1407-CFC, 2020 WL 708113, at *1 (D. Del. Feb. 12, 2020).

Grace also asserts that Elysium should not benefit from practicing the “wait-and-see” approach. D.I. 257 at 8-9. However, Elysium was not aware of the additional facts at the time of the original pleading and did not simply choose not to include them. *See, e.g., In re Digital Island Sec. Litig.*, C.A. No. 02-57-GMS, 2002 WL 31667863, at *1 (D. Del. Nov. 25, 2002), *aff’d*, 357 F.3d 322 (3d Cir. 2004) (finding plaintiff’s decision to oppose the motion to dismiss in its entirety instead of seeking leave to amend was “highly suspect as the plaintiffs were aware of the facts which they now seek to add at the time the original pleading was filed.”). Rather, the depositions of Mr. Short and Mr. Reynolds were taken after the Amended Answer and Counterclaims was filed, D.I. 113, and after the briefing on the Motion to Dismiss, D.I. 136, had concluded. Thus, there is good cause for leave to amend.

2. Rule 15 Analysis

Having found good cause for leave to amend, the Court next analyzes the Rule 15 factors. With respect to prejudice, the Court is taking the parties at their word that no additional discovery is required and thus Grace will not be prejudiced by additional discovery. D.I. 288, ¶ 18. The Court notes that Grace was on notice of the inequitable conduct claim against Mr. Short. D.I. 152 at 7 (“Elysium’s pleading [of inequitable conduct] identifies individuals by name,

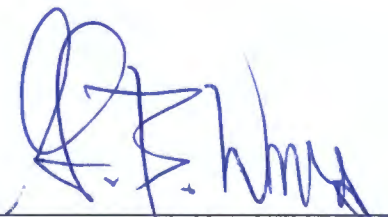
including . . . [6] David Short, Grace’s Global Business & Technology Manager[.]”). Elysium’s expert reports named David Short in their analyses addressing inequitable conduct. *See* D.I. 240, Ex. 10 (Perni Opening Report) at ¶ 225 (“Messrs. Carlson, Short and Reynolds at a minimum . . . had the intent not to disclose this invalidating information to the US PTO.”); D.I. 240; Ex. 11 (Steed Opening Report) at ¶¶ 205, 207; D.I. 240, Ex. 12 (Armitage Opening Report) at ¶¶ 41, 87, 96, 99 n.86, 100, 103. Also, Grace’s own patent expert, Dr. Kunin, recognized that David Short was one of the individuals at Grace accused of violating their duties under PTO Rule 56. D.I. 240, Ex. 14 (Kunin Rebuttal Report) at ¶ 93. *See also id.* at ¶¶ 146-149, 160. Thus, the Court finds that there will be no prejudice to Grace with the amendment.

The Court also finds that there was no undue delay by Elysium for the same reasons it finds that good cause exists for the amendment. *See supra* § II.2.b.1.⁵ Finally, the Court finds that there is no evidence of bad faith or evidence that the amendment would be futile. In fact, Grace makes no arguments concerning bad faith or futility in its opposition to Elysium’s Motion. *See generally* D.I. 257.

III. CONCLUSION

For all these reasons, the Court GRANTS Elysium’s Motion for Leave to Amend its Answer and Counterclaims.

Date: September 22, 2023



GREGORY B. WILLIAMS
UNITED STATES DISTRICT JUDGE

⁵ *See Fraunhofer-Gesellschaft*, 2018 WL 3425012, at *3. *See also Benati v. Matevousian*, 2020 WL 58041, at *3 (E.D. Cal. Jan. 6, 2020) (acknowledging similarities between Rule 15 undue delay and Rule 16(b) diligence analyses).